

## **REMARKS**

Claims 14-23 are now pending in the present application. Claims 1-13 have been canceled. Claims 14-20 have been amended. Reconsideration of the claims is respectfully requested.

### **I. Claim Objections**

The Examiner has objected to claims 14 and 18 due to misspellings. These claims have been appropriately amended to correct the typographical errors.

### **II. 35 U.S.C. §112, first paragraph**

Claims 14-23 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

With respect to claims 14-23, the Office Action states in part:

In new claim 14, the recited range of 4-nerolidylcatechol ("a range from 0.005 to 20.2%") within the instantly claimed composition is deemed new matter. That is, the specification (including the original claims) supports a range from 0.005 to 20.0% (see, e.g., original claims 5 and 8). However, the Examiner could not find support for an upper range of 20.2% (as set forth in new claim 14) within the instant specification.

Applicant is required to cancel the new matter in the reply to this Office Action or, alternatively, to particularly point to adequate support for this upper range limitation.

Claim 14 has been amended appropriately to include the upper limit of 20.0%.

The Office Action further states:

In addition, the instant specification fails to provide an adequate written description with respect preparing a standardized extract of *Pothomorphe umbellata* which when added to a composition provides an overall composition containing the instantly claimed ranges of 4-nerolidylcatechol (on the basis of the standardized extract) therein. That is, the specification appears to be silent in terms of describing to one of skill in the art how to make the instantly claimed standardized extract of *Pothomorphe umbellata* as it relates to an overall composition containing 0.005 to 20.0% of 4-nerolidylcatechol (in the form of the extract) therein. It should be noted that the instant specification alludes to the fact that the antioxidant activity demonstrated by various prior art *Pothomorphe umbellata* extract preparations may be due to not just to [sic] the compound 4-nerolidylcatechol, but also to the presence of other additional compounds within such extract preparations that contribute to their

observed enhance antioxidant activity – as compared to the antioxidant activity by the isolated compound 4-nerolidylcatechol alone (see, e.g., page 6, line 25 – page 7, line 5 of the instant specification) – which would also suggests [sic] that the steps by which the recited “standardized extract” is prepared would necessarily be essential in terms of making a standardized extract of *Pothomorphe umbellata* for incorporation into an overall composition containing 0.005 to 20.0% (or 20.2%) of 4-nerolidylcatechol (contained within the standardized extract) therein (as instantly claimed) – including with respect to its functional (enhanced antioxidant) ability to treat the various skin afflictions instantly claimed (further, without this information, how would the skilled artisan properly compare/distinguish prior art *Pothomorphe umbellata* extract preparations from the instantly claimed *Pothomorphe umbellata* extract preparation? – see art rejections below for additional information).

Accordingly, the instant specification lacks an adequate description as to the essential extraction steps necessary to actually prepare a “standardized extract of *Pothomorphe umbellata*” which contains the instantly claimed ranges of 4-nerolidylcatechol therein.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983); *In re Herschler*, 591 F.2d 693, 701, 200 U.S.P.Q. 711, 717 (CCPA 1979); *In re Edwards*, 558 F.2d 1349, 1351, 196 U.S.P.Q. 465, 467 (CCPA 1978).

The instant specification teaches:

[0029] Another aspect of the present invention refers to the dermocosmetic and/or pharmaceutical composition, which comprises as an active ingredient, the *P. umbellata* root extract. Composition shall be considered as the group formed by the active principle and the other ingredients (pharmaceutically acceptable excipient) that form the carrier, as well as any product that results, direct or indirectly, from the dissociation of one or more of the ingredients, or of other types of reactions or interactions of one or more of the ingredients.

[0030] The composition, exemplified in the form of a dermocosmetic, according to the proposed invention, can be prepared in accordance with prior art methods, for topical use. This example illustrates the chosen formulation, but it does not intend to limit the invention in any way. A proposed composition is comprised of:

[0031] a) carboxymethylcellulose 0.01-10.0%

[0032] b) propyleneglycol 0.001-50.0%

[0033] c) methylparaben 0.001-3.0%

[0034] d) Pothomorphe umbellata standardized extract, so that the formulation contains 0.005 to 20.0% of 4-nerolidylcatechol

[0035] e) distilled water q.s.p. 100.0%

[0036] For the preparation of an effective composition, it is necessary that the extract standardization in regard to the amount of 4-nerolidylcatechol present therein. This is made in a high efficiency chromatography device coupled to an electrochemistry detector or UV detector.

[0037] The preparing of the composition of this invention can be made through any known methods in the pharmacy art and in combination with an [sic] pharmaceutical carrier, in accordance with the conventional techniques of pharmaceutical composition. The proposed composition is presented in the form of gel. But the presentation can be made in several forms, depending on the preparing possibility for the desired topical use, for instance, for the lips, labial protective, for the body, protective lotions for the body, lotion, moisturizers, among others. After standardizing the extract in regard to its concentration of 4-nerolidylcatechol, then, it is incorporated in the cosmetic and/or pharmaceutical bases, so that to reach the desired active principle concentration.

[0039] The carrier, in addition to the mentioned ones in the proposed composition, can be a solvent or a dispersion medium containing, for example: water, ethanol, polyol (for example, glycerol, propylene glycol and liquid polyethylene glycol), appropriate mixtures and vegetable oils. In addition to aforementioned the ingredients, the described pharmaceutical formulations can include, in an appropriate way, one or more carrier ingredients, such as diluents, buffers, ligands, surface active agents, thickeners, preservatives (including anti-oxidizers) and similar and inclusion of other substances.

Though the specification does not lay out the process step by step, as explained above the standardized extract of the present invention can be prepared using methods well known in the art. One of ordinary skill in the art does not need to have these methods of preparing the composition explicitly spelled out step by step, but rather only needs to know the compounds to use and the proper concentrations to achieve and can

then apply known methods to produce them. Therefore, the instant specification conveys to one of ordinary skill in the art that the inventor had possession of the claimed invention, and the written description requirement is satisfied.

The Examiner's comments regarding the antioxidant activity of other compounds possibly found in *Pothomorphe umbellata* is irrelevant with regard to 35 USC §112, first paragraph. As explained in paragraph 0036, the efficacy of the present invention relies specifically on the use of *Pothomorphe umbellata* extract with a 4-nerolidylcatechol concentration of 0.005 to 20.0%. It is this concentration of 4-nerolidylcatechol (which one skilled in the art can produce using known methods) that forms the basis upon which one of ordinary skill the art can distinguish and compare the extract of the present invention with prior art extracts of *Pothomorphe umbellata*.

Claims 20-23 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement.

With respect to claims 20-23, the Office Action states in part:

[C]laims 20-23 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for treating the various claimed skin afflictions, does not reasonably provide enablement for preventing such skin afflictions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims...

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed *Pothomorphe umbellata* extract in a manner commiserate with preventing the various recited skin afflictions, as instantly claimed.

Claims 20-23 have been amended to remove the limitation of preventing the skin afflictions in question.

Therefore, it is respectfully asserted that the rejection of claims 14-23 under 35 USC §112, first paragraph has been overcome and should be withdrawn.

### **III. 35 U.S.C. §112, second paragraph**

Claims 14-23 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

With respect to claims 14-23, the Office Action states in part:

Claim 14 is rendered vague and indefinite by the phrase “a standardized extract of *Pothomorphe umbellata* which contains 4-nerolidylcatechol a range of 0.005-20.2% in the composition.”...

Claims 14 and 20 are rendered vague and indefinite by the phrase “[C]omposition on basis of Pothomorphe umbellata extract” (line 1 of claim 14 and lines 1-2 of claim 20)...

Claims 15-17 are rendered vague and indefinite by the phrase “comprising a composition which is presented for ...”...

Claim 20 is also rendered vague and indefinite by the phrase “topically administered in a way to allow satisfactory therapeutic response” (lines 3-4).

Claims 21-23 are rendered vague and indefinite by the phrase “comprising an ... activity” because these claims depend from the method of claim 20...

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Though the Applicants believe that one skilled in the art would understand the bounds of the claim when read in light of the specification, the claims have been amended to facilitate prosecution.

Therefore, it is respectfully asserted that the rejection of claims 14-23 under 35 USC §112, second paragraph has been overcome and should be withdrawn.

#### IV. 35 U.S.C. §102, Anticipation

Claims 14-17 and 20-23 are rejected under 35 U.S.C. §102(b) as being anticipated by Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002).

With respect to claims 14-17 and 20-23, the Office Action states in part:

The cited reference teaches a topical gel composition comprising an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 0.1% 4-nerolidylcatechol (on the basis of the Pothomorphe umbellata extract) therein. This reference also teaches topically applying the gel compositions to the skin of hairless mice (see Abstract #S527). Please note that the topical application of the reference extract gel

preparation would inherently provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claims 14-17 and 20-23 are rejected under 35 U.S.C. §102(b) as being anticipated by Ropke et al. (Annals of the 14<sup>th</sup> National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000).

With respect to claims 14-17 and 20-23, the Office Action states in part:

The cited reference teaches a topical gel compositions presented in a gel form (i.e., within diadermine – an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein. This reference also teaches topically applying the topical compositions to the skin of hairless mice (see entire English translation including pages 2-5, 7-9, 13-14, 16, and final paragraph on page 18). Please note that the topical application of the reference extract topical preparation would inherently provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claims 14-17 and 20-23 are rejected under 35 U.S.C. §102(a) as being anticipated by Ropke et al. (Intl. J. Pharmaceutics, December 2002).

With respect to claims 14-17 and 20-23, the Office Action states in part:

The cited reference teaches a topical gel composition comprising an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 0.1% 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract) therein. This reference also teaches topically applying the gel compositions to the skin of hairless mice (see entire document). In addition, this reference discloses that in a previous study, they evaluated *P. umbellata* extracts incorporated into topical formulations so as to provide final concentrations of 0.05, 0.1, 0.2, and 2% 4-nerolidylcatechol therein (see page 110, first column, of the first cited reference). Please note that the topical application of the reference extract gel preparation would inherently provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Therefore, the cited reference is deemed to anticipate the instant claims above.

A prior art reference anticipates the claimed invention under 35 U.S.C. §102 only

if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). All limitations of the claimed invention must be considered when determining patentability. *In re Lowry*, 32 F.2d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994).

The current set of claims overcomes all rejections as none of the Ropke et al. references teaches or suggests the limitation of 2.1 to 20.0% by weight of 4-nerolidylcatechol in the composition.

Therefore, it is respectfully asserted that the rejection of claims 14-17 and 20-23 under 35 USC §102 has been overcome and should be withdrawn.

#### **V. Claim Rejections – 35 U.S.C. §102/103**

Claims 14 and 15 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as unpatentable over Barros et al. (Ciencia e Cultura, 1996) or over Desmarchelier et al. (Planta Med, 1997).

With respect to claims 14 and 15, the Office Action states in part:

Each of the cited references teaches a composition comprising an alcoholic (ethanolic – Barros et al.; methanolic – Desmarchelier et al.) extract of *Pothomorphe umbellata* having strong antioxidant activity (such as instantly disclosed) which each reference expressly discloses contain the compound 4-nerolidylcatechol – apparently within the instantly claimed percentage range (as best understood) – therein (see entire documents). Please note that given the lack of guidance (written description) provided by the instant specification in terms of making the instantly claimed *Pothomorphe umbellata* extract (as discussed above), the reference extract compositions each appear to be the same as that instantly claimed (as best understood). Consequently, the claimed *Pothomorphe umbellata* extract appears to be anticipated by each of the cited references.

In the alternative, even if the claimed *Pothomorphe umbellata* extract is not identical to the referenced *Pothomorphe umbellata* extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Pothomorphe umbellata* extracts are likely to inherently possess the same characteristics of the claimed *Pothomorphe umbellata* extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Pothomorphe umbellata* extract would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. §103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

A prior art reference anticipates the claimed invention under 35 U.S.C. §102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). All limitations of the claimed invention must be considered when determining patentability. *In re Lowry*, 32 F.2d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994).

Neither the Barros et al. reference nor the Desmarchelier et al. reference teaches or suggests the limitation of 2.1 to 20.0% by weight of 4-nerolidylcatechol in the composition.

The Examiner's reference regarding the lack of guidance in making the claimed composition has been addressed above. The specific composition of the claimed extract is clearly stated in the specification and recited in the claims. Neither the Barros et al. reference nor the Desmarchelier et al. reference teaches or suggests this specific composition.

The mere fact that the prior art could be readily modified to arrive at the claimed invention does not render the claimed invention obvious; the prior art must suggest the desirability of such a modification. *In re Ochiai*, 71 F.3d 1565, 1570, 37 U.S.P.Q.2d 1127, 1131 (Fed. Cir. 1996); *In re Gordon*, 733 F.2d 900, 903, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Merely stating that the modification would have been obvious to one of ordinary skill without identifying an incentive or motivation for making the proposed modification is insufficient to establish a *prima facie* case.

The Examiner merely states that the claimed extract would have been obvious to one of ordinary skill without identifying an incentive to standardize the reference extract to contain the instantly claimed range of 4-nerolidylcatechol. The merely presence of 4-nerolidylcatechol in the compositions disclosed in Barros et al. and Desmarchelier et al. does not obviously lead to the specific concentrations recited in claim 14, nor has the Examiner cited any sections of the references that would suggest use of the concentration level recited in claim 14.



As the Examiner failed to support his rejection of claims 14 and 15 with a specific citation to any motivation for the modification in any reference, Examiner is respectfully invited to either withdraw the rejection of claims 14 and 15 or provide a specific citation to a reference disclosing a motivation for modifying the reference extracts to obtain the claimed invention.

Claims 14, 15, and 20-23 are also rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Uchiyama et al. (JP 2001122763) – with evidence provided by Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997).

With respect to claims 14, 15, and 20-23, the Office Action in part states:

Uchiyama et al. teach a topical skin composition comprising an extract of *Pothomorphe umbellata* (including an alcoholic extract such as an ethanolic or methanolic extract – please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol – see entire documents) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin (please also not that topical application of the reference *Pothomorphe umbellata* extract would inherently prevent the recited skin afflictions, as instantly claimed), including applying to human skin fibroblasts. Uchiyama et al. also teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) – such as instantly disclosed (see entire English translation including paragraphs [0007]-[0016], [0021], [0028], [0034]-[0035], [0037], and Tables). Again, please note that given the lack of guidance (written description) provided by the instant specification in terms of making the instantly claimed *Pothomorphe umbellata* extract (as discussed above), the reference extract composition appears to be the same as that instantly claimed (as best understood). Consequently, the claimed *Pothomorphe umbellata* extract appears to be anticipated by the cited reference.

In the alternative, even if the claimed *Pothomorphe umbellata* extract is not identical to the referenced *Pothomorphe umbellata* extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Pothomorphe umbellata* extracts are likely to inherently possess the same characteristics of the claimed *Pothomorphe umbellata* extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Pothomorphe umbellata* extract would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. §103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

If the document relied by the Examiner upon in support of a rejection is in a language other than English, a translation must be obtained so that the record is clear as to the precise facts the Examiner is relying upon. MPEP §706.02II. Although Examiner included a computer assisted translation of Uchiyama, the translation fails to disclose all of the relevant facts and information in English. The Examiner relies upon paragraphs in Uchiyama that cite to tables and the Tables in support of his rejection, but the tables are not fully translated in English. As such, the Uchiyama et al. reference may not be cited as prior art. The Examiner is respectfully invited to either withdraw his rejection of claims 14 and 15 or provide a fully translated document.

Therefore, it is respectfully asserted that the rejection of claims 14, 15, and 20-23 under 35 USC §§102, 103 has been overcome and should be withdrawn.

#### VI. **35 U.S.C. §103, Obviousness**

Claims 14-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14<sup>th</sup> National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000) in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art. This rejection is also respectfully traversed.

With respect to claims 14-23, the Office Action states in part:

The two cited Ropke et al. references each beneficially teach a topical gel compositions having strong therapeutic antioxidant activity which comprises an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract) within the instantly claimed ranges therein. These references also teach topically applying the gel compositions to the skin of hairless mice (see Abstract #S527 of first Ropke et al. reference; and entire English translation including pages 2-5, 7-9, 13-14, 16, and final paragraph on page 18 of the second Ropke et al. reference). Neither of the Ropke et al. references expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 – col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use – such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) – including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note that the topical application of such an extract gel preparation would intrinsically provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Thus, the invention as a whole was clearly *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of evidence to the contrary.

As explained above, the present invention in claim 14 recites the limitation of a range of 2.1 to 20.0% 4-nerolidylcatechol in the composition. Such a concentration is not taught or suggested by either of the Ropke references and extends significantly outside the concentration discussed by Ropke. The Examiner has conveniently ignored the specific concentrations of 4-nerolidylcatechol disclosed in Ropke and those recited in claim 14 and has not provided any substantive argument regarding the motivation to make such a significant change from the concentration discussed in the prior art to that recited in claim 14.

The present invention is directed towards a skin gel to be applied topically that contains a *Pothomorphe umbellata* extract with 2.1 to 20.0% of 4-nerolidylcatechol in the

composition, alone and incorporated into a cosmetic composition. The Ropke et al. references teach a *Pothomorphe umbellata* extract which contains 0.1 to 2% of 4-nerolidylcatechol. Wheeler teaches that carboxymethylcellulose, propylene glycol, and methylparaben may be used in the aqueous phase of a composition which also contains a bi-liquid foam. A combination of either of the Ropke et al. references and Wheeler would not form the presently claimed invention. Instead, a combination of either of the Ropke et al. references and Wheeler would result in a composition containing a bi-liquid foam layer and an aqueous layer which contains the *Pothomorphe umbellata* extract for antioxidant activity. As the references cited would not combine to make the presently claimed invention, the presently claimed invention is not obvious.

In determining obviousness, an applicant's teachings may not be read into the prior art. *Panduit Corp. v. Denison Mfg. Co.*, 810 F.2d 1561, 1575 n. 29, 1 U.S.P.Q. 1593, 1602 n. 29 (Fed. Cir. 1987) (citing need to "guard against hindsight and the temptation to read the inventor's teachings into the prior art"). A determination of the desirability of combining or modifying prior art references must be made without the benefit of hindsight afforded by an applicant's disclosure. *In re Paulsen*, 30 F.3d 1475, 1482, 31 U.S.P.Q. 1671, 1676 (Fed. Cir. 1994).

Based on the teachings of the Ropke et al. references and Wheeler, it was not obvious that the conventional ingredients and the *Pothomorphe umbellata* extract would result in a useful composition without the bi-liquid foam layer taught by Wheeler. It is known from the applicants' teachings and disclosure, not the teachings of prior art, that a useful composition may be made of only carboxymethylcellulose, propylene glycol, methylparaben, *Pothomorphe umbellata* extract with the claimed range of 4-nerolidylcatechol, and distilled water, without the additional bi-liquid layer in the composition.

At best, the proposed motivation for the modification of the combination of the teachings of either of the Ropke et al. references and Wheeler constitutes a statement of why the modification is obvious to try. Nothing in those references suggests a reasonable expectation of success.

Claims 14-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Uchiyama (JP 2001122763) in view of Barros et al. (Ciencia e Cultura, 1996) and

Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

With respect to claims 14-23, the Office Action states in part:

Uchiyama et al. beneficially teach a topical skin composition (e.g., in the form of a lotion, cream, etc.) comprising an extract of *Pothomorphe umbellata* (including an alcoholic extract such as an ethanolic or methanolic extract – please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin. Uchiyama et al. also beneficially teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) – such as instantly disclosed (see entire English translation including paragraphs [0007]-[0016], [0021], [0028], [0034]-[0035], [0037], and Tables).

The Barros et al. and Desmarchelier et al. references each beneficially teach a composition comprising an alcoholic (ethanolic – Barros et al.; methanolic – Desmarchelier et al.) extract of *Pothomorphe umbellata* – whereby the extracts demonstrate strong antioxidant activity (such as instantly disclosed) which contain the compound 4-nerolidylcatechol – apparently within the instantly claimed percentage range (as best understood) – therein (see entire documents including *Abstract and Material and Methods*).

None of the above references, including Uchiyama et al., expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 – col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use – such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of *Pothomorphe umbellata* within the skin therapeutic composition (having antioxidant activity) as taught by Uchiyama et al., especially since Uchiyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such alcoholic solvents provide a *Pothomorphe umbellata* extract having strong

antioxidant activity (in addition, it should again be noted that, as evidenced by Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol therein). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate such a *Pothomorphe umbellata* extract into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) – including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selections and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of evidence to the contrary.

If the document relied by the Examiner upon in support of a rejection is in a language other than English, a translation must be obtained so that the record is clear as to the precise facts the Examiner is relying upon. MPEP §706.02II. Although Examiner included a computer assisted translation of Uchiyama, the translation fails to disclose all of the relevant facts and information in English. The Examiner relies upon paragraphs in Uchiyama that cite to tables and the Tables in support of his rejection, but the tables are not fully translated in English. As such, the Uchiyama et al. reference may not be cited as prior art. The Examiner is respectfully invited to either withdraw his rejection of claims 14-19 or provide a fully translated document.

In comparing Barros et al. or Desmarchelier et al. to the claimed invention to determine obviousness, limitations of the presently claimed invention may not be ignored. The present invention in claim 14 recites the limitation of a range of 2.1 to 20.0% 4-nerolidylcatechol in the composition. Such a limitation is not taught or suggested by Barros et al. or Desmarchelier et al. as explained above.

Therefore, it is respectfully asserted that the rejection of claims 14-23 under 35 USC §103 has been overcome and should be withdrawn.

## CONCLUSION

In light of the amendments and the arguments made by Applicants above, as well as the evidence previously submitted, Applicants submit that all existing, examined claims are now in a condition for allowance. Applicants respectfully request that Examiner withdraw all restrictions and rejections with regard to the above-referenced claims in reliance on one or more of the grounds submitted by Applicants.

If there are any outstanding issues that the Examiner feels may be resolved by way of telephone conference, the Examiner is invited to call David Carstens at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

The Commissioner is hereby authorized to charge any payments that may be due or credit any overpayments to CARSTENS & CAHOON, LLP Deposit Account 50-0392.

Respectfully submitted by:



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Dated: September 24, 2007